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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/733,534

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EXAMINER

MOSS, KERI A

ART UNIT

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1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/733,534	<b>Applicant(s)</b> GJERDE ET AL.	
	<b>Examiner</b> KERI A. MOSS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-28 and 41-53 is/are pending in the application.
- 4a) Of the above claim(s) 29-34, 38-40 and 43-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-28, 41-42 and 49-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 29-34 and 38-40 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 20, 2008.
2. Applicant's election with traverse of Group II in the reply filed on May 20, 2008 is acknowledged. The traversal is on the ground(s) that Groups II and III stem from a common concept and theory and are very closely related. This is not found persuasive because in applicants' specification, applicants refer to the different embodiments of their invention (paragraph [188]). One embodiment involves adding the protein complex to the extraction surface (the invention of Group II) whereas the other embodiment involves forming the protein complex on the extraction surface (the invention of Group III) (paragraph [188]). Thus, the groups are distinct and would require an undue examination and search burden.

The requirement is still deemed proper and is therefore made FINAL.

3. Newly submitted claims **43-48** are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the previously searched invention did not comprise elution with a solid phase extraction tube

enrichment factor great than 1 or 2. Regarding claims 45-48, the previously claimed invention did not comprise an extraction channel that is a capillary.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 43-48 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Response to Amendment***

4. The rejections under Laursen et al. (USP 6,429,192) and Hagen et al. (USP 4,810,381) have been withdrawn in light of applicants' amendments.

#### ***Claim Objections***

5. Claims **19, 22, 43 and 44** are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims replace the method step c) of claim 14 and thus should be rewritten in independent form.

#### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1797

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims **19, 22, 43 and 44** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims contradict the subject matter of claim 14 by replacing the method step c) of claim 14. Clarification is required.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims **14 and 17-18** are rejected under 35 U.S.C. 102(e) as being anticipated by Agnew et al (US Pub 2004/0171034). Agnew et al. teaches a method for extracting a multi-protein complex comprising the steps of introducing a sample solution comprising the multi-protein complex into an extraction channel which has an inner surface comprising an extraction surface that binds the multi-protein complex, passing a wash solution through the channel and passing a first desorption solution through the channel, thereby eluting the first protein (paragraph [0014]).

10. Claims **14, 17-20, 22-24, 26-28, 41-42 and 49-53** are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmerman et al. (USP Re. 32,011).

Zimmerman teaches a method for extracting a multi-protein complex comprising the steps of introducing a sample solution comprising the multi-protein complex into an extraction channel which has an inner surface comprising an extraction surface that binds the multi-protein complex, passing a wash solution through the channel and passing a first desorption solution through the channel, thereby eluting the first protein (column 2 line 55-column 3 line 13). The second protein remains adsorbed (column 3 lines 3 lines 3-4). The multi-protein complex comprises a protein antigen (abstract). A second desorption solution is passed through the extraction channel, thereby eluting the second protein (column 8 lines 49-53). The first and second desorption solutions differ in ionic composition (column 2 line 55-column 3 line 13; column 8 lines 49-53). The first desorption solution inherently contains an agent that effects protein-protein interactions. The desorption solutions are inherently flowed back and forth through the column due to fluid dynamics. The extraction surface is 3-dimensional and is comprised of an affinity binding agent consisting of a protein (column 6 lines 9-36). The method is performed in a plurality of channels operated in parallel or in a solid block having one or more passageways running through (columns 7-8).

***Claim Rejections - 35 USC § 103***

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims **15-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al. or Agnew et al, supra, in view of Gobom et al (Sample Purification and Prepartio technique Based on nano-scale Reversed-phase Columns for the Sensitive Analysis of Complex Peptide Mixtures by Matrix-assisted laser Desorption/Ionization Mass Spectrometry, J. Mass Spectrom., vol 34 pages 105-116 (1999)). Neither Zimmerman nor Agnew expressly teach purging the extraction channel with a gas prior to passing a desorption solution through the channel wherein the extraction surface remains substantially solvated after the purging step. Gobom et al. teach a method of extracting proteins wherein the extraction channel is purged with a gas before adding the desorption solution (page 107, right column). Gobom teaches that this step is imperative for smooth and continuous liquid flow in the next step (page 107, right column). Thus, it would have been obvious to modify Zimmerman or Agnew by purging the channel with gas before adding the desorption solution in order to gain the predictable results of a smooth and continuous liquid flow during the purification of the protein.

13. Claim **21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al., supra. See Zimmerman supra. Zimmerman does not expressly

teach using a third desorption solution to elute a third protein. However, Zimmerman provides all the necessary teaching for eluting more than one protein in a protein complex (column 2 line 55-column 3 line 13; column 8 lines 49-53). It would have been obvious for one of ordinary skill in the art to modify Zimmerman by using a third desorption solution to elute a third protein in order to obtain the predictable results of separating the third protein from the multi-protein complex.

14. Claim **25** is rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al, supra, in view of Agnew et al, supra. Zimmerman does not expressly teach an agent selected from urea, guanidinium chloride and isothiocyanate. Agnew teaches purifying a protein by using an agent comprising reactive groups that bind to phosphate by interfering with protein-protein interactions (paragraphs [0104-0106]). These reactive groups include isothiocyanates and ureas (paragraph [0106]). The advantage of these reactive groups is that they are photoactivatable (paragraph [0154]). The advantage of photoactivatable reactive groups is that the resulting phosphate-binding compound that is useful for conjugation to phosphorylated target molecules (paragraph [0153]). Therefore, it would have been obvious to modify Zimmerman with the reactive groups of Agnew et al. in order to gain the advantages of having a resulting phosphate-binding compound that is useful for conjugation to phosphorylated target molecules.



15. Claims **26-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al., supra, in view of Strosberg et al. (EP 1 178 318 A1). Strosberg teaches using a multi-protein complex that comprises a recombinant bait protein comprising a fusion tag (column 37 line 38- column 39 line 60). Strosberg teaches that these recombinant bait proteins can be used as marker compounds, which have the art-recognized benefit of providing a visible method of determining whether two compounds have interacted. Strosberg also teaches that the benefit of these recombinant bait proteins is that they bind specifically to the polypeptide of interest. Therefore, it would have been obvious for one of ordinary skill in the art to use a recombinant bait protein with a fusion tag in order to bind to a specific polypeptide of interest and to gain the additional advantages and predictable result of optically determining when that polypeptide has been bound to the recombinant bait protein.

### ***Response to Arguments***

16. Applicant's arguments with respect to claims 1-40 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797

/Keri A. Moss/  
Examiner, Art Unit 1797